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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,135	10/18/2006	Amar Lulla	PAC/23225 US (4137-00600)	8688
30652	7590	05/08/2009	EXAMINER	
CONLEY ROSE, P.C. 5601 GRANITE PARKWAY, SUITE 750 PLANO, TX 75024			WESTERBERG, NISSA M	
			ART UNIT	PAPER NUMBER
			1618	
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			05/08/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,135	<b>Applicant(s)</b> LULLA ET AL.	
	<b>Examiner</b> Nissa M. Westerberg	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 - 35, 53 is/are pending in the application.
- 4a) Of the above claim(s) 4 - 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 3, 11 - 35, 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' arguments, filed March 24, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

#### ***Election/Restrictions***

1. Applicant submits that claims 4 – 8 should be afforded examination as these claims further define and limit the elected species of claim 1. If an election of a species such as alendronate sodium trihydrate had been made, these claims would not have been withdrawn. Applicant, however, in the response filed on July 25, 2008, elected the active ingredient of alendronic acid. This compound does not read on claims 4 – 8, these claims were properly withdrawn from consideration.

#### ***Claim Rejections - 35 USC § 112 – 1<sup>st</sup> Paragraph***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims 1 – 3 and 11 – 35 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Due to the amendments to the claims, this rejection is withdrawn.

***Claim Rejections - 35 USC § 112 – 2<sup>nd</sup> Paragraph***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 34 and 35 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 24, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that 21,066 issued patents recite the phrase “substantially free” in the claims and 811 patents reciting the phrase “intimately mixing”. Thus, the rejection should be withdrawn.

This argument is not persuasive. Each case is examined individually on the merits of that particular case. These terms or phrases can be present in the claims if a definition of these terms is present, for example, by stating what level of contamination or purity would meet the limitations ‘substantially free’. As Applicants have not defined these terms, this rejection is maintained.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 – 3, 11 – 22, 25 – 32, 34 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/03963 (Jasprova). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 24, 2008 and those set forth below.

Applicant traverse this rejection on the grounds that Jasprova fails to disclose an intragranular phase as the method of Jasprova does not teach a granulation step, is free of granulation or pre-granulation components. Also, the formulation of Jasprova usually includes a dry binder, not the aqueous binder of the instant claims. As all of the claimed elements are not recited, the instant claims cannot be anticipated.

These arguments are not persuasive. The instant claims are product claims and are not directed towards a method of making the claimed composition. The compositions disclosed by Jasprova disclose the same physical constituents in the same “phase” of the composition, although they are produced by a different process. As detailed in the instant specification, the binder is applied as an aqueous solution to granulate the product, and the water is then removed by a drying (p 10 of the instant specification). The dry binder of Jasprova and the aqueous binder of the instant claims

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are the same chemical compounds, they are just introduced into the composition in a dry or moistened state, but the final product in both cases in a solid oral formulation. In order for process steps to patentably distinguish a product claim over the cited prior art, the product made by the two processes must be shown to be different or nonobvious over each other. Such evidence has not been submitted so this rejection is maintained.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 – 3, 11 – 34 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/03963 (Jasprova) in view of Flash-Ner-Barak et al. (WO 02/00204). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 24, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that neither reference contains an aqueous binder. Flash-Ner-Barak et al. teaches the use of superdisintegrants that swell upon contact with water and one of ordinary skill in the art would readily understand that the superdisintegrant would absorb the water of the aqueous binder, resulting in swelling of the tablet during manufacture, so the final product would fail to provide upon ingestion a “tablet that is retained in the stomach for an extended period of time by swelling to a size that prevents passage through the pylorus upon contact with gastric juices.” As Flash-Ner-Barak et al. cannot teach an aqueous binder, it cannot remedy the shortcomings of Jasprova.

These arguments are not persuasive. As discussed in greater detail above, the limitations of “aqueous binder” is met by Jasprova. Applicant argues that the application of water to a solution containing a superdisintegrant such as sodium starch glycolate and the subsequent absorption of water by this ingredient would result in swelling of the

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tablet during manufacture. The Examiner notes that in the tablet formulations described in the instant specification, Applicant successfully applies an aqueous solution to granules containing the superdisintegrant sodium starch glycolate, that after drying, are compressed into tablets (p 11 – p 12). Therefore, the Examiner requires a more detailed explanation of how the products produced by the process described in the instant specification and the process used by the cited prior art result in patentable distinct products. The instant claims and the primary reference do not require a tablet dosage form retained in the stomach.

12. Claims 1 – 3, 11 – 34 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jasprova and Flash-Ner-Barak et al. further in view of Katdare et al. (WO 95/29679). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 24, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Katdare et al. does not contain an aqueous binder as it disclose that binder is not necessary in a bisphosphonic acid composition.

These arguments are not persuasive. As discussed in greater detail above, the disclosure of Jasprova and Flash-Ner-Barak et al. meet the limitation regarding an aqueous binder in the composition and thus Katdare et al. is not required to teach an aqueous binder.



***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. This application contains claims 4 – 10 drawn to an invention nonelected with traverse in the reply filed on July 25, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

NMW